II. REMARKS

A. Status of the Claims

Claims 1-14, 17, 22-24 and 27 were amended without prejudice or admission. Support for the upper limit of the amount of naltrexone recited in claims 1 and 22 (i.e., 0.28 mg) can be found, e.g., in paragraph [0015] of the specification.

New claims 30-36 were added. Support for new claims 30-35 can be found, e.g., in paragraph [0042] of the specification. Support for new claim 36 can be found, e.g., in paragraphs [0116] to [0130] of the specification.

Applicants respectfully submit that no new matter was added by virtue of the present amendments.

Claims 1-36 will be pending once the present amendment is entered.

B. Claim Rejections- 35 U.S.C. § 103

1. U.S. 2003/0229111 to Oshlack et al.

Claims 1-14, 17-19, 22, 27-29 were rejected under 35 U.S.C. § 103(a) over U.S. 2003/0229111 to Oshlack et al..

The rejection is respectfully traversed, for the reasons set forth in the response filed on January 4, 2010, hereby incorporated by reference, and for the additional reasons given below.

Independent claims 1 and 22 recite, in part, that the ratio of naltrexone to hydrocodone in the claimed compositions is "from 0.011:1 to 0.0125:1."

Independent claim 27 recites, in part, that the ratio of naltrexone to hydrocodone in the claimed compositions is "0.0125:1."

Applicants respectfully submit that the cited reference does not suggest the desirability of the claimed ratios and does not render these ratios obvious.

In response to the Examiner's statement on page 4 of the Office Action that "it is obvious to vary and/or optimize the amount of hydrocodone and naltrexone provided in the composition ...," Applicants submit that "obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition." See *Ex parte* Whallen II, Appeal No. 2007-4423 (Board of Patent Appeals and Interferences 2008).

The Examiner has not pointed to any teaching in the cited reference that would support the conclusion that those skilled in the art would have considered it obvious to "optimize" the compositions described in the cited reference by lowering the naltrexone to hydrocodone ratio in the hydrocodone/naltrexone compositions of the cited reference.

Applicants respectfully note that the naltrexone to hydrocodone ratios in the hydrocodone/naltrexone compositions described in the cited reference are higher than the ratios recited in the present claims. For example, the naltrexone to hydrocodone ratio in Example 22 of the cited reference is 0.025:1, which is double the highest naltrexone to hydrocodone ratio recited in the present claims (i.e., 0.0125:1). The naltrexone to hydrocodone ratio of Example 20 of the cited reference is 0.1:1, which is eight times higher than the 0.0125:1 ratio recited in the present claims.

Accordingly, Applicants submit that the cited reference does not describe the claimed ratio and does not provide a reason for the skilled person to formulate a composition comprising naltrexone and hydrocodone in the claimed ratios.

With further regard to claims 2-11, Applicants submit that the cited reference does not provide a reason for the skilled person to formulate a dosage form containing the relative amounts of naltrexone and hydrocodone recited in these claims.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

2. U.S. 2003/0191147 to Sherman et al. in view of U.S. 2003/0031712 to Kaiko et al.

Claims 1-29 were rejected over the combination of U.S. 2003/0191147 to Sherman et al. and U.S. 2003/0031712 to Kaiko et al..

The rejection is respectfully traversed, for the reasons set forth in the response filed on January 4, 2010, hereby incorporated by reference, and for the additional reasons given below.

Applicants respectfully submit that the combination of the cited references does not render the presently claimed naltrexone to oxycodone ratios obvious, as the claimed ratios are outside the naltrexone to oxycodone ratios of the hydrocodone/naltrexone compositions described in the cited references.

Applicants respectfully submit that the ratio of naltrexone to hydrocodone in Example 15 of the Sherman publication (i.e., 0.01:1) is at least 10% lower than the lowest ratio recited in independent claims 1 and 22 (i.e., 0.011:1) and is 25% lower than the ratio recited in independent claim 27 (i.e., 0.125:1). Accordingly, Applicants submit that the ratio of naltrexone to hydrocodone in Example 15 of the Sherman publication does not meet the limitations of the naltrexone to hydrocodone ratios of independent claims 1, 22 and 27.

Applicants further submit that the naltrexone to hydrocodone ratio in Tables 1 and 2 of the Kaiko reference also does not meet the limitations of the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27. In Tables 1 and 2 in the Kaiko reference, the weight ratio naltrexone per 1 mg of hydrocodone recited is "0.033 to 0.267," with a preferred ratio being "0.050 to 0.200." Applicants respectfully submit that this ratio is outside the ratio range recited in independent claims 1, 22 and 27, and is 2.6 times higher[1] than the 0.0125:1 ratio recited in claims 1, 22 and 27.

Accordingly, Applicants respectfully submit that the combination of the cited references does not describe the naltrexone to hydrocodone ratios recited in independent claims 1, 22 and 27, and therefore does not suggests the desirability of the claimed ratios.

In response to the Examiner's statement on page 2 of the Advisory Action that "[i]t is well within the routine skill of the art to take the teachings of the prior are dealing with the ranges taught and formulate them in different ratios for effective treatment ...," Applicants respectfully reiterate that "obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition." See *Ex parte* Whallen II, Appeal No. 2007-4423 (Board of Patent Appeals and Interferences 2008).

Applicants respectfully submit that the combination of the cited references does not provide such a reason in the present case.

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

[1] 0.033/0.0125=2.64.

III. Conclusion

An early and favorable action is earnestly solicited. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone if the Examiner believes that a telephonic interview may advance the prosecution of the application.

Respectfully submitted,
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